11 June 1999

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Subject: Comments on Proposed Amendment

Ref: Docket No. 93N-0044

This letter is to express support for the proposed harmonization of the CDRH Laser Product Performance Standard with the IEC 825-1 laser safety standard. A set of comments and recommendations for improvement of the proposal is also included.

Harmonization of the US regulations with those outside of this country will be of benefit to both manufacturers and users. Manufacturers will be able to build and label their products to a single set of requirements, with the knowledge that they will be satisfying the applicable regulations. Users and regulators will have only one classification scheme to consider when determining the needed control measures.

There are two areas of general concern, however, with respect to this proposal. As your agency is aware (through the extensive involvement of the CDRH representative), the IEC TC-76 committee has proposed significant amendments to the IEC 825-1 standard. Those amendments are currently undergoing the approval process as IEC document 76/196/CDV, and if they are adopted, the revised IEC standard could be in effect in the year 2000. It is recommended that your agency delay adoption of these proposed CDRH amendments until the status of the IEC proposal is known. That short delay would allow your agency to evaluate the IEC proposal and to determine if a re-proposal of amendments to your standard would be appropriate in order to be compatible with the IEC amendments. It would be unfortunate indeed for the CDRH to revise their standard to harmonize with a document that was soon to be obsolete.

The second area of concern relates to the classification change from IIIa to 3b for small-beam lasers with visible outputs in the 1-5 mW range. As the proposal is drafted, such products would be adversely impacted by the human access definition in 1040.10 b(14), by the interlock requirements in f(2)(iii)(A), and by construction laser limits of 1040.11(b). Even if those paragraphs are revised to eliminate the impact of this change on such products, a significant problem would occur with respect to user laser safety standards. The ANSI 136.1 standard, state regulations, and industrial laser safety standards typically rely on the CDRH classification scheme, and they place many more restrictions and apply more control measures (including appointment of a Laser Safety Officer) on Class 3b than on Class 3a installations. Thus purchasers of laser pointers, many construction instruments, and most other current Class IIIa

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products would be subjected to a level of user regulation for Class 3b that would be expensive and inconvenient, with no real increase to public safety. Thus it is recommended that the proposal be revised to allow products which are currently Class IIIa to remain within the proposed Class 3a classification. This concern will likely disappear if the above-described IEC proposal is approved and the CDRH then adopts those changes, since such products will fall under a new Class 3R.

If you need any clarification on these comments, please contact me.

Yours truly,

Bob Weiner

Enclosure

cc: Jerome Dennis (HFZ-312)

b "Angular subtense" and "apparent source" are essential to the proposal and are included in other definitions, but they are not defined. Those in 3.6 and 3.8 of IEC 825-1 could be considered (also, 76/196/CDV amends the 3.6 definition).

It may be appropriate to include definitions for "beam diameter" and "beam divergence" to clarify that they are the 1/e values - see 3.10 & 3.11 in IEC 825-1.

b(14) The use of the possible reflection from an introduced flat surface to determine access is specified for all Class 3b products. But Table 3 places most current CDRH Class IIIa products into 3b. If those products are not to remain 3a under this proposal, to be consistent with IEC and with current CDRH IIIa this definition should include the exemption for visible beams that do not exceed 5X the Class 2 limits as specified in 3.32a of IEC 825-1. Also see the comments in the attached letter.

b(26) For consistency with IEC, change 0.01 rad to 0.011 rad. Also correct "less than or equal to 10 s" to "t greater than or equal to 10 s". Add definition of t or add reference to b(35).

d(4)(i) Add: "long-term" after "intentional" to be consistent with 9.3e of IEC 825-1

d(4)(ii) As above, add: "long-term" after "intentional" to be consistent with 9.3e of IEC 825-1

e(3)(i)(C) This paragraph and the following formula appear not to be needed since e(3)(i)(B) specifies that a 100 mm distance for measurements can be used. In the Note that follows, e(3)(i)(C) can deleted.

f(1) For the Note, see the comment above to b(14). It might be better to simply refer to the definition in b(14) (once it is corrected).

f(2)(i)(A) The proposal exceeds the requirement in IEC 4.3.1(b) that exempts visible beams that do not exceed 5X the Class 2 limits from the need for interlocks on 3B and 4 products. Recommend to add the equivalent exemption.

f(2)(iii)(A) The proposal also exceeds the current regulations for IIIa in that it requires redundant interlocks for all products that contain 3b energy inside, including that for visible beams that do not exceed 5X the Class 2 limits. Recommend that redundant interlocks not be needed for these products.

f(5)(ii) Is the paragraph as proposed still needed? What is not included in the proposal is the second half of the current f(5)(iii) that discusses requirements for "operation controls" that went into effect after 1986.

This does not include the requirements in IEC 4.6.2 and 4.6.3 for multiple apertures and for spacing between operating controls and lasers.

f(6) This requirement is more stringent than IEC in that it requires attenuation to Class 1 (although the IEC standard should be written as "Class 1, Class 2, **and** Class 3a") [this difference probably does not have any practical impact]

g(2)(ii) The warning statement: "Avoid Direct Eye Exposure" is limited to 5 mW under the current CDRH regulations. As written, the proposal would apply that wording up to the Class 3b limit in the visible (e.g., 500 mW). Should not that also include the: "with not more than 5 times Class 2" statement?

g(5) The aperture label is specified for all products which exceed Class 1 and Table 7. But the introductory paragraph of g states that IEC labeling is acceptable, and the IEC does not require an aperture label for Class 2 and 3a (or for collateral radiation). Also, the IEC allows: "Laser Aperture" to be used as an alternate wording. It is recommended to delete the aperture label requirement for Class 2 and 3a and to include the alternate wording allowed.

g(6) The large number of subtle variations in label wording creates confusion and thus results in product non-compliances with little or no increase in public safety. It is recommended to replace all of the protective housing labels with a generic statement to warn of laser energy inside (e.g., "Caution: Laser radiation inside").

g(7) As noted for g(6), it is recommended simplifying all defeatably-interlocked protective housing labels to: "Caution: Laser radiation inside when interlock defeated").

h(2)(i) The IEC standard allows in 6.2 that only the class need be stated in the sales literature. It does not require a reproduction of the warning logotype. (That requirement does include Class 1.) Recommend that the proposal be revised to allow only the class be stated.

H(2)(ii) The last sentence specifies the need to reproduce all required labels (thus including the ID/certification labels). Recommend to revise the last line to: "labels required by paragraph (g) and hazard warnings" in order to eliminate the need to reproduce that label.

1040.11

a(1) This requirement exceeds that from the IEC standard which does not require an aperture label for Class 2 and 3a

b As written, the proposal would preclude the use of current CDRH Class IIIa products for construction/alignment applications. This could have a significant negative impact on sale of products that have been in the marketplace for many years. And that would be more restrictive than the user section of the IEC standard. Recommend: Allow Class 3b with visible beams that do not exceed 5X the Class 2 limits.

As noted in the attached letter, this points out a problem with the revision to the Class 3a limits - the ANSI and state user standards will make it difficult to use the many (current) Class IIIa construction instruments. It may also raise havoc if they attempt to apply Class IIIb control measures (including laser safety officers and controlled access areas) to users of most laser pointers.

c This is confusing as written and would not likely achieve the intended restriction. Recommend the following revision: "….for a Class 1, 2, 3A, or 3B laser. It shall not permit human access to levels exceeding five times the AEL of Class 2 in the wavelength range of 400-700 nm and shall not permit human access to levels above the AEL of Class 1 at other wavelengths."

Table 1 Add "nm" in the upper left corner after wavelength symbol.

In 400-700 row, change subscript to superscript for 0.75. Add C_6 in 10 s column of that row.

In 1050-1400 row, change 3X to 2X in the <10-9 column

In the rows below 1400, for time periods > 10-7s, move the time divisions all one column to the left.

Table 3 Add "nm" in the upper left corner after wavelength symbol.

In the 400-700 row and the fourth column, add $t^{0.75}$ for radiant exposure.

In the 700-1050 row, In the fourth column, add $t^{0.75}$ for radiant exposure.

Table 7 The time period of 1000 seconds in 1(ii) is not consistent with the change to 100 s for classification. Recommend to revise to 100 s.

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FIRST CLASS MAIL

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